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Baseline Characteristics Module

Results Database Train-the-Trainer Workshop
October 2012

http://ClinicalTrials.gov

FDAAA - Baseline Measures

"A table of the demographic and baseline data collected overall and for each arm of the clinical trial…"

[Sec. 282(j)(3)(C)(i)]

FDAAA = Food and Drug Administration Amendments Act of 2007

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Description of Baseline Characteristics Module

- Table of demographic and baseline data for the entire trial population and for each arm or comparison group
- Accommodates different data types:
  - **Continuous**: measure of central tendency (e.g., mean) and measure of dispersion (e.g., standard deviation)
  - **Categorical**: for each category - (1) a count or (2) measure of central tendency and measure of dispersion

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"Table 1" Journal Article Format

Table 1. Baseline characteristics of the modified intention-to-treat population in a phase II randomized trial of amphotericin B alone or combined with fluconazole in the treatment of human immunodeficiency virus (HIV)–associated cryptococcal meningitis.

Variable	AmB (n = 46)	AmB+Fluc400 (n = 48)	AmB+Fluc800 (n = 41)
Country			
Thailand	32 (69.6)	34 (70.8)	31 (75.6)
United States	14 (30.4)	14 (29.2)	10 (24.4)
Age, mean years ± SD	36.5 ± 8.52	36.4 ± 8.69	35.8 ± 9.36
Sex			
Male	30 (65.2)	31 (64.6)	26 (63.4)
Female	16 (34.8)	17 (35.4)	15 (36.6)
Race			
Asian/Thai	32 (69.6)	34 (70.8)	31 (75.6)
Black	8 (17.4)	10 (20.8)	3 (7.3)
White	4 (8.7)	4 (8.3)	6 (14.6)
Other	2 (4.4)	0	1 (2.4)
CD4+ T cell count, median cells/mm³ (range)	18 (1–123)	17 (0–80)	15 (0–94)
Viral load, median copies/mL (range)	272,000 (400–1,342,580)	369,000 (50–1,000,000)	169,000 (216–1,000,000)
Opening pressure			
>250 mm CSF	22 (47.8)	26 (54.2)	22 (53.7)
≤250 mm CSF	20 (43.5)	19 (39.6)	17 (41.5)
Not done	4 (8.7)	3 (6.3)	2 (4.9)
CSF cryptococcal antigen titer, median (range)	2048 (4–32768)	1024 (4–71024)	1024 (4–16384)
MMSE, mean score ± SD	25.5 ± 5.21	25.3 ± 5.07	23.4 ± 7.25
Received prestudy fluconazole and/or flucytosine[a]			
Yes	6 (13.0)	4 (8.3)	2 (4.9)
No	40 (87.0)	44 (91.7)	39 (95.1)
Receipt of antiretroviral therapy			
Yes	5 (10.9)	3 (6.2)	3 (7.3)
No	41 (89.1)	45 (93.8)	38 (92.7)

Pappas PG, Chetchotisakd P, Larsen RA et al. Clin Infect Dis. 2009

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ClinicalTrials.gov Format

Baseline Measures

	AmphoB Standard	AmphoB+Fluc400	AmphoB + Fluc800	Total
Number of Participants [units: participants]	45	47	49	141
Age [units: participants]				
<=18 years	0	0	1	1
Between 18 and 65 years	45	47	47	139
>=65 years	0	0	1	1
Age [units: years] Mean ± Standard Deviation	37.1 ± 8.47	36.5 ± 8.21	35.9 ± 9.44	36.5 ± 8.69
Gender [units: participants]				
Female	16	15	18	49
Male	29	32	31	92
Region of Enrollment [units: participants]				
United States	14	14	14	42
Thailand	31	33	35	99

"Default" Required Measures

NCT00145249

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ClinicalTrials.gov Format

User-Specified Baseline Measures

Hormonal Receptor Status [units: Participants]			
Positive	1348	1346	2694
Negative	301	303	604
Karnofsky Performance Status at Baseline [units: Participants]			
80 - Activity with effort; some signs of disease	36	33	69
90 - Normal activity; minor signs of disease	315	323	638
100 - Normal no complaints; no evidence of disease	1298	1293	2591
Menopausal status [units: Participants]			
Pre-Menopausal or Other age < 50 Years	866	863	1729
Post-Menopausal or Other age > 50 Years	783	786	1569
Number of Positive Lymph Nodes [units: Participants]			
[0]	0	1	1
[1 to 3]	1010	1005	2015
[4 to 10]	462	456	918
> 10	177	187	364

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Baseline Characteristics Template
Age

Arm/Group Title *		*		*		*
Arm/Group Description ①						
Overall Number of Baseline Participants *		*		*		*
Age, Categorical ②	Number of Participants		Number of Participants		Number of Participants	
Unit of Measure: Participants						
<=18 years		[*]		[*]		[*]
Between 18 and 65 years		[*]		[*]		[*]
>=65 years		[*]		[*]		[*]
Age, Continuous ②	Measure Type [*]	Dispersion/ Precision Type [*]	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type
	(Circle One) Mean, Median, Least Squares Mean, Geometric Mean, Log Mean	(Circle One) Standard Deviation, Inter-quartile Range, Full Range				
Unit of Measure: [*]	[*]	③[*]	[*]	③[*]	[*]	③[*]
Age, Customized ②	Measure Type [*]	Dispersion/ Precision Type [*]	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type
	(Circle One) Number, Mean, Median, Least Squares Mean, Geometric Mean, Log Mean	(Circle One) Not Applicable④, Standard Deviation, Inter-quartile Range, Full Range				
Unit of Measure: [*]						
Category Title⑤: [*]	[*]	③[*]	[*]	③[*]	[*]	③[*]
Category Title⑤: [*]	[*]	③[*]	[*]	③[*]	[*]	③[*]

Baseline Characteristics Template
Study Specific Measure

Study Specific Baseline Measure Title	[*]					
Baseline Measure Description						
Arm/Group Title*	*		*		*	
Arm/Group Description ①						
Overall Number of Baseline Participants*	*		*		*	
Unit of Measure: [*]	Measure Type [*] (Circle One) Number, Mean, Median, Least Squares Mean, Geometric Mean, Log Mean	Dispersion/ Precision Type [*] (Circle One) ② Not Applicable, Standard Deviation, Inter-quartile Range, Full Range	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type
Category Title④: [*]	[*]	③[*]	[*]	③[*]	[*]	③[*]
Category Title④: [*]	[*]	③[*]	[*]	③[*]	[*]	③[*]

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Best Practices

- Minimum requirements
  - Age and Gender
- Region of Enrollment
- Other relevant demographic characteristics
- Clinical measures relevant to study, such as
  - Clinical characteristics, including baseline values of outcome measures
  - Prior and concurrent treatment characteristics

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Baseline Characteristics *Tutorial*

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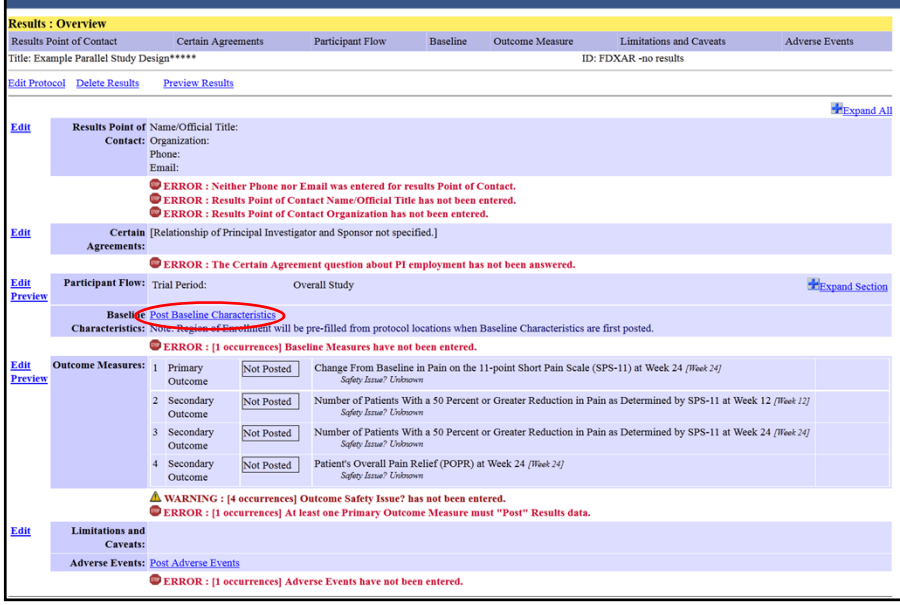
Post Baseline Characteristics



Results : Overview

Results Point of Contact | Certain Agreements | Participant Flow | Baseline | Outcome Measure | Limitations and Caveats | Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Edit Protocol Delete Results Preview Results

Expand All

Edit **Results Point of Contact:** Name/Official Title:
Organization:
Phone:
Email:

ERROR : Neither Phone nor Email was entered for results Point of Contact.
ERROR : Results Point of Contact Name/Official Title has not been entered.
ERROR : Results Point of Contact Organization has not been entered.

Edit **Certain Agreements:** [Relationship of Principal Investigator and Sponsor not specified.]

ERROR : The Certain Agreement question about PI employment has not been answered.

Edit Preview **Participant Flow:** Trial Period: Overall Study — Expand Section

Baseline Characteristics: Post Baseline Characteristics
Note: Region of Enrollment will be pre-filled from protocol locations when Baseline Characteristics are first posted.

ERROR : [1 occurrences] Baseline Measures have not been entered.

Edit Preview **Outcome Measures:**

1	Primary Outcome	Not Posted	Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24 *[Week 24]* *Safety Issue? Unknown*
2	Secondary Outcome	Not Posted	Number of Patients With a 50 Percent or Greater Reduction in Pain as Determined by SPS-11 at Week 12 *[Week 12]* *Safety Issue? Unknown*
3	Secondary Outcome	Not Posted	Number of Patients With a 50 Percent or Greater Reduction in Pain as Determined by SPS-11 at Week 24 *[Week 24]* *Safety Issue? Unknown*
4	Secondary Outcome	Not Posted	Patient's Overall Pain Relief (POPR) at Week 24 *[Week 24]* *Safety Issue? Unknown*

WARNING : [4 occurrences] Outcome Safety Issue? has not been entered.
ERROR : [1 occurrences] At least one Primary Outcome Measure must "Post" Results data.

Edit **Limitations and Caveats:**

Adverse Events: Post Adverse Events

ERROR : [1 occurrences] Adverse Events have not been entered.

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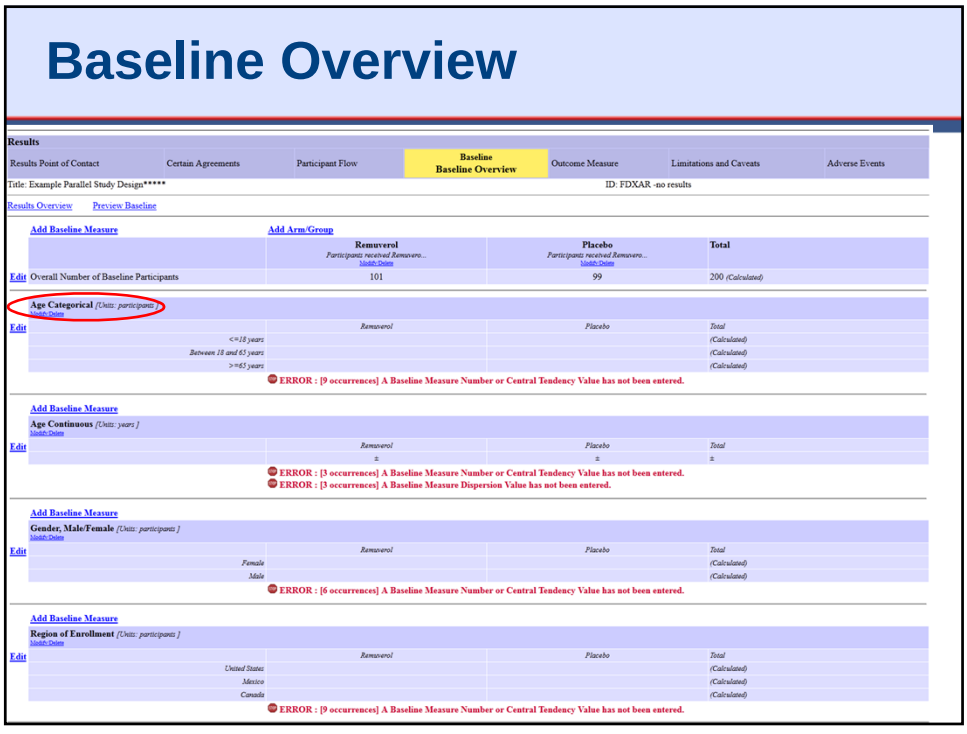
Baseline Overview



Results

Results Point of Contact | Certain Agreements | Participant Flow | **Baseline** **Baseline Overview** | Outcome Measure | Limitations and Caveats | Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Results Overview Preview Baseline

Add Baseline Measure Add Arm/Group

		Remuverol *Participants received Remuvero...* Modify Delete	Placebo *Participants received Remuvero...* Modify Delete	Total
Edit	Overall Number of Baseline Participants	101	99	200 *(Calculated)*

Age Categorical *[Units: participants]* Modify Delete

	Remuverol	Placebo	Total
Edit <=18 years			*(Calculated)*
Between 18 and 65 years			*(Calculated)*
>=65 years			*(Calculated)*

ERROR : [9 occurrences] A Baseline Measure Number or Central Tendency Value has not been entered.

Add Baseline Measure

Age Continuous *[Units: years]* Modify Delete

	Remuverol	Placebo	Total
Edit	±	±	±

ERROR : [3 occurrences] A Baseline Measure Number or Central Tendency Value has not been entered.
ERROR : [3 occurrences] A Baseline Measure Dispersion Value has not been entered.

Add Baseline Measure

Gender, Male/Female *[Units: participants]* Modify Delete

	Remuverol	Placebo	Total
Edit Female			*(Calculated)*
Male			*(Calculated)*

ERROR : [6 occurrences] A Baseline Measure Number or Central Tendency Value has not been entered.

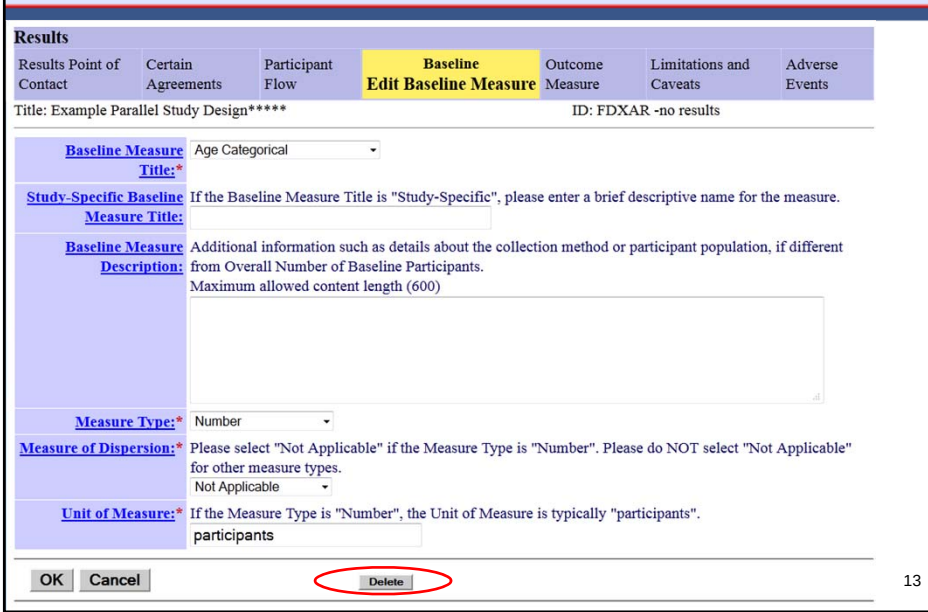
Add Baseline Measure

Region of Enrollment *[Units: participants]* Modify Delete

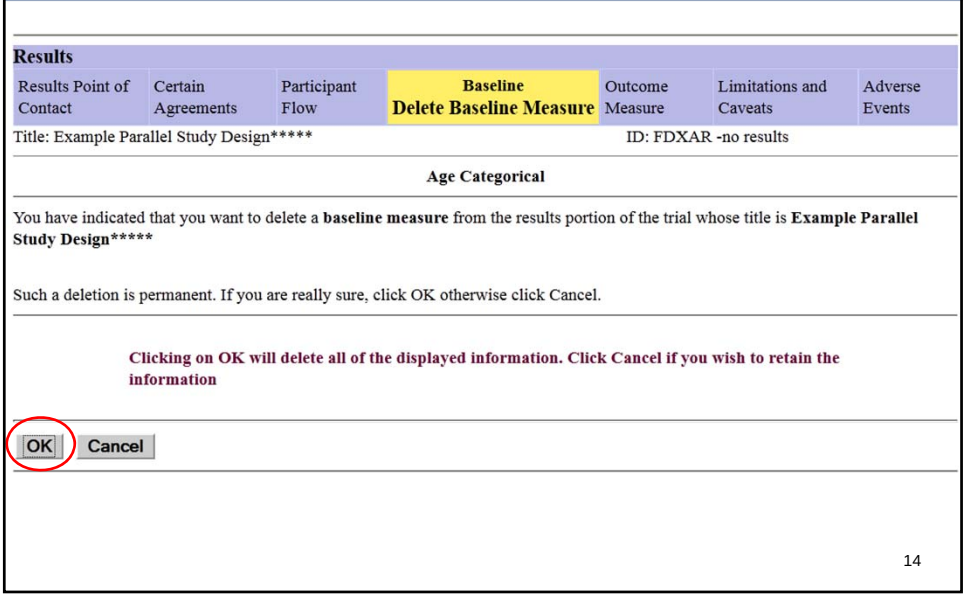
	Remuverol	Placebo	Total
Edit United States			*(Calculated)*
Mexico			*(Calculated)*
Canada			*(Calculated)*

ERROR : [9 occurrences] A Baseline Measure Number or Central Tendency Value has not been entered.

Edit Baseline Measure



Delete Baseline Measure



Baseline Overview

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Baseline Overview**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Results Overview Preview Baseline

Add Baseline Measure Add Arm/Group

		Remuverol *Participants received Remuvero...* Modify/Delete	Placebo *Participants received Remuvero...* Modify/Delete	Total
Edit	Overall Number of Baseline Participants	101	99	200 *(Calculated)*

Age Continuous *[Units: years]* Modify/Delete

		Remuverol	*Placebo*	*Total*
Edit		±	±	±

ERROR : [3 occurrences] A Baseline Measure Number or Central Tendency Value has not been entered.
ERROR : [3 occurrences] A Baseline Measure Dispersion Value has not been entered.

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Baseline Measure

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Baseline Measure**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Baseline Overview

Age Continuous

Create Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

Overall Number of Baseline Participants	101	99	*200 (Calculated)*
Age Continuous *[Units: years]*	**Remuverol** *Participants received Remuvero...*	**Placebo** *Participants received Remuvero...*	**Total**
Edit	<> (<>) **ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.** **ERROR : A Baseline Measure Dispersion Value has not been entered.**	<> (<>) **ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.** **ERROR : A Baseline Measure Dispersion Value has not been entered.**	<> (<>) **ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.** **ERROR : A Baseline Measure Dispersion Value has not been entered.**

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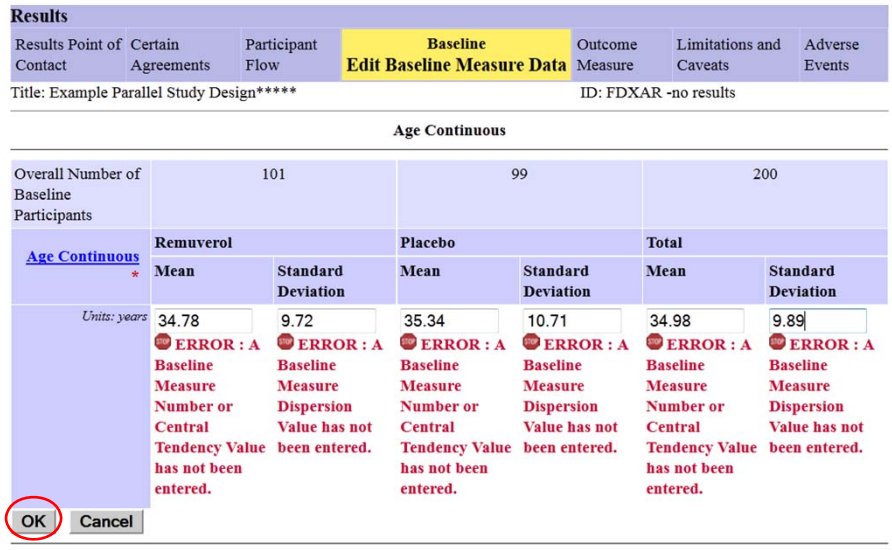
Edit Baseline Measure Data



Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Edit Baseline Measure Data**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Age Continuous

Overall Number of Baseline Participants	101		99		200	
Age Continuous *	**Remuverol**		**Placebo**		**Total**	
	Mean	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**
Units: years	34.78	9.72	35.34	10.71	34.98	9.89
	ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	**ERROR : A Baseline Measure Dispersion Value has not been entered.**	**ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.**	**ERROR : A Baseline Measure Dispersion Value has not been entered.**	**ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.**	**ERROR : A Baseline Measure Dispersion Value has not been entered.**

OK Cancel

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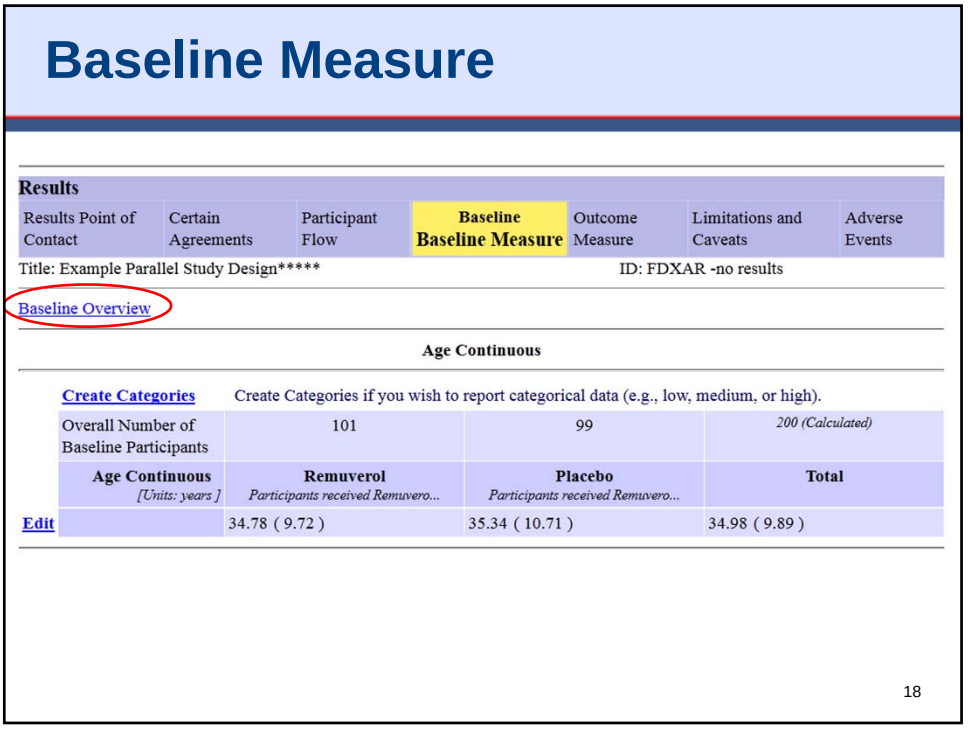
Baseline Measure



Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Baseline Measure**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Baseline Overview

Age Continuous

Create Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

	Overall Number of Baseline Participants	101	99	*200 (Calculated)*
	Age Continuous *[Units: years]*	**Remuverol** *Participants received Remuvero...*	**Placebo** *Participants received Remuvero...*	**Total**
Edit		34.78 (9.72)	35.34 (10.71)	34.98 (9.89)

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Baseline Overview

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Baseline Overview**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Results Overview Preview Baseline

Add Baseline Measure Add Arm/Group

		Remuverol *Participants received Remuvero...* Modify/Delete	Placebo *Participants received Remuvero...* Modify/Delete	Total
Edit	Overall Number of Baseline Participants	101	99	200 *(Calculated)*

	Age Continuous *[Units: years]* Modify/Delete			
Edit		*Remuverol*	*Placebo*	*Total*
		34.78 ± 9.72	*35.34 ± 10.71*	*34.98 ± 9.89*

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Add Baseline Measure

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Add Baseline Measure**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Baseline Measure Title:* Study Specific Characteristic

Study-Specific Baseline Measure Title: If the Baseline Measure Title is "Study-Specific", please enter a brief descriptive name for the measure.
Quebec Task Force Classification of Spina

Baseline Measure Description: Additional information such as details about the collection method or participant population, if different from Overall Number of Baseline Participants.
Current length: 141 [Maximum allowed content length: 600]

Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis).

Measure Type:* Number

Measure of Dispersion:* Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.
Not Applicable

Unit of Measure:* If the Measure Type is "Number", the Unit of Measure is typically "participants".
participants

OK Cancel

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Baseline Measure

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Baseline Measure**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Baseline Overview

Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]

Create Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

	Overall Number of Baseline Participants	101	99	*200 (Calculated)*
	Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] *[Units: participants]*	**Remuverol** *Participants received Remuvero...*	**Placebo** *Participants received Remuvero...*	**Total** *(=sum across Arm/Groups)*
Edit		<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
	Total (=sum across categories)	*(Calculated)*	*(Calculated)*	*(Calculated)*

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Add Baseline Measure Category

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Add Baseline Measure Category**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]

Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen.
Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure).

Category Title*	Class 0 (no pain)
New Category Title*	Class 1 (pain)

OK Cancel

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Baseline Measure

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Baseline Measure**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Baseline Overview

Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]

Create Category Reorder Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

	Overall Number of Baseline Participants	101	99	*200 (Calculated)*
	Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] *[Units: participants]*	**Remuverol** *Participants received Remuvero...*	**Placebo** *Participants received Remuvero...*	**Total** *(=sum across Arm/Groups)*
Edit	**Class 0 (no pain)** Modify/Delete	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
	Class 1 (pain) Modify/Delete	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
	Total (=sum across categories)	*(Calculated)*	*(Calculated)*	*(Calculated)*

Add Baseline Measure Category

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline** **Add Baseline Measure Category**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]

Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen.
Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure).

Category Title*	Class 0 (no pain)
Category Title*	Class 1 (pain)
New Category Title*	Class 2 (pain with radiation to lower limb)

OK Cancel

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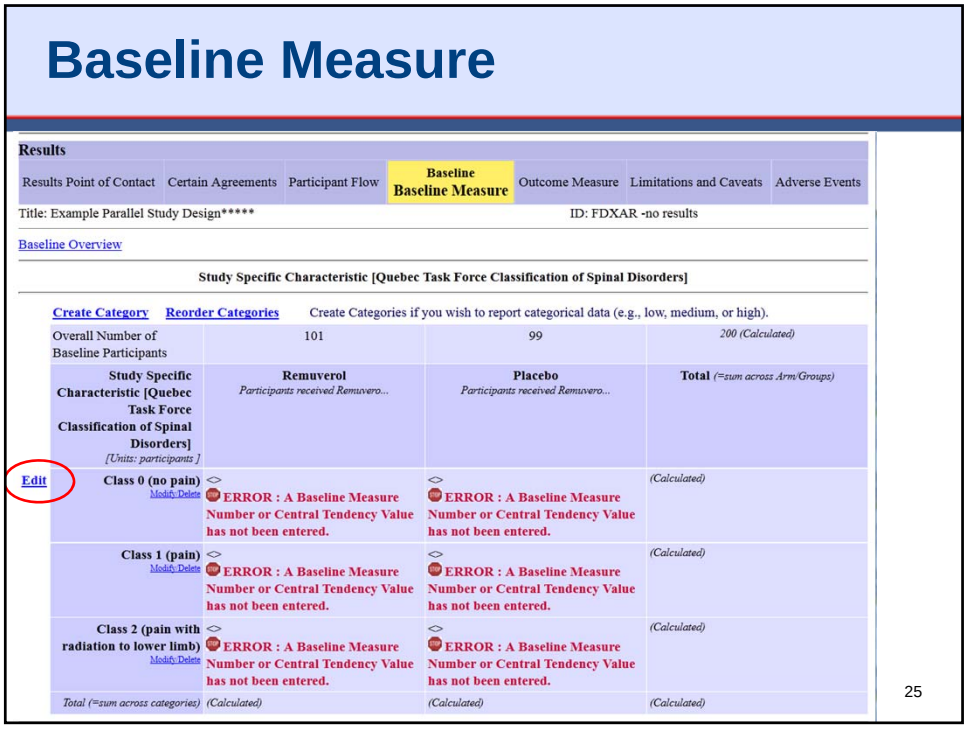
Baseline Measure



Results

Results Point of Contact | Certain Agreements | Participant Flow | **Baseline** **Baseline Measure** | Outcome Measure | Limitations and Caveats | Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Baseline Overview

Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]

Create Category | Reorder Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

Overall Number of Baseline Participants	101	99	*200 (Calculated)*
Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] *[Units: participants]*	**Remuverol** *Participants received Remuvero...*	**Placebo** *Participants received Remuvero...*	**Total** *(=sum across Arm/Groups)*
Edit — **Class 0 (no pain)** Modify/Delete	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
Class 1 (pain) Modify/Delete	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
Class 2 (pain with radiation to lower limb) Modify/Delete	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	<> ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
Total (=sum across categories)	*(Calculated)*	*(Calculated)*	*(Calculated)*

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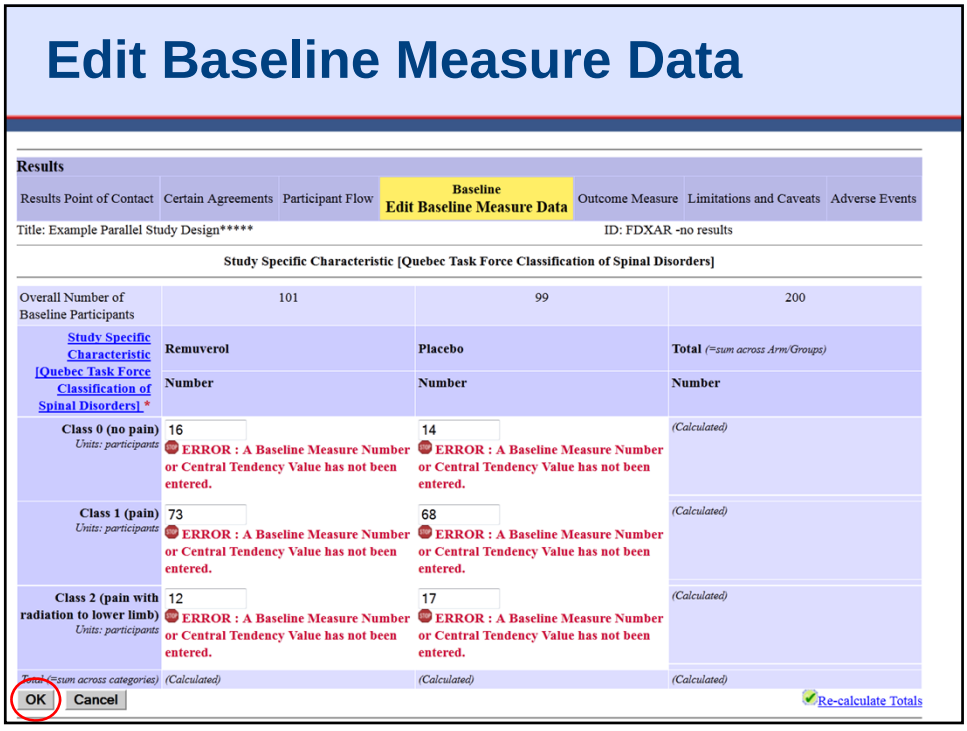
Edit Baseline Measure Data



Results

Results Point of Contact | Certain Agreements | Participant Flow | **Baseline** **Edit Baseline Measure Data** | Outcome Measure | Limitations and Caveats | Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]

Overall Number of Baseline Participants	101	99	200
Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] *	**Remuverol** **Number**	**Placebo** **Number**	**Total** *(=sum across Arm/Groups)* **Number**
Class 0 (no pain) *Units: participants*	16 ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	14 ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
Class 1 (pain) *Units: participants*	73 ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	68 ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
Class 2 (pain with radiation to lower limb) *Units: participants*	12 ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	17 ERROR : A Baseline Measure Number or Central Tendency Value has not been entered.	*(Calculated)*
Total (=sum across categories)	*(Calculated)*	*(Calculated)*	*(Calculated)*

OK | Cancel Re-calculate Totals

Baseline Measure

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline Baseline Measure**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Baseline Overview

Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]

Create Category Reorder Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

	Overall Number of Baseline Participants	101	99	*200 (Calculated)*
	Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders] *[Units: participants]*	**Remuverol** *Participants received Remuvero...*	**Placebo** *Participants received Remuvero...*	**Total** *(=sum across Arm/Groups)*
Edit	**Class 0 (no pain)** Modify/Delete	16	14	*30 (Calculated)*
	Class 1 (pain) Modify/Delete	73	68	*141 (Calculated)*
	Class 2 (pain with radiation to lower limb) Modify/Delete	12	17	*29 (Calculated)*
	Total (=sum across categories)	*101.0 (Calculated)*	*99.0 (Calculated)*	*200.0 (Calculated)*

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Baseline Overview

Results

Results Point of Contact	Certain Agreements	Participant Flow	**Baseline Baseline Overview**	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Results Overview Preview Baseline

Add Baseline Measure Add Arm/Group

		Remuverol *Participants received Remuvero...* Modify/Delete	**Placebo** *Participants received Remuvero...* Modify/Delete	**Total**
Edit	Overall Number of Baseline Participants	101	99	200 *(Calculated)*

	Age Continuous *[Units: years]* Modify/Delete			
Edit		*Remuverol*	*Placebo*	*Total*
		34.78 ± 9.72	*35.34 ± 10.71*	*34.98 ± 9.89*

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Enter Baseline Characteristics

- Example Study Designs
  - Crossover
  - Dose Escalation
  - Factorial
  - Multiple Period

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Additional Issues

- More than one Period (or time point) is considered "baseline"

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